

Remarks

In view of the above amendments and the following remarks, reconsideration of the outstanding office action is respectfully requested.

Claims 1, 6, 9, 12, and 13 have been amended, and claims 11, 14-18, and 54 have been cancelled without prejudice. The amendment to claim 1 is supported by original claim 3, and the amendments to claims 6, 9, 12, and 13 modify their dependency (to depend from allowable claim 53). Therefore, no new matter is introduced by these amendments.

New claims 55-58 have been introduced. New claims 55 and 56 depend from claim 1, and find descriptive support in original claims 4 and 5. New claims 57 and 58 depend from allowable claim 53, and find support in original claims 19 and 48. Therefore, no new matter is introduced by these amendments.

No excess claim fees are due with this submission.

Claims 1, 4, 5, 6, 9, 12, 13, 19-22, 48-53, and 55-58 are pending, although claims 48-53 (and new claim 58) stand withdrawn. Because all claims under examination are now allowable for the reasons noted below, claims 48-53 and 58 should be rejoined and allowed.

The rejection of claims 1, 6, 9, 12, 13, 19-22, and 54 under 35 U.S.C. § 112 (1st para.) for failing to comply with the written description requirement is rendered moot with respect to claim 54 and is otherwise overcome by the amendments presented herein.

Claim 1 has been amended to recite that the substituted "glutamic acid residue correspond[s] to position 113 of SEQ ID NO: 2." Applicant submits that this satisfies the written description requirement for claim 1 and claims 19-22 dependent thereon, because one of skill in the art would fully appreciate that applicants were in possession of recombinant factor VIII proteins having the recite glutamic acid substitution. The several Examples, including Example 14, demonstrate as much.

Claims 6, 9, 12, and 13 now depend from allowable claim 53.

For these reasons, the rejection of claims 1, 6, 9, 12, 13, 19-22, and 54 under 35 U.S.C. § 112 (1st para.) for lack of written description should be withdrawn.

The rejection of claims 1, 6, 9, 12, 13, 19-22, and 54 under 35 U.S.C. § 112 (1st para.) for lack of enablement is rendered moot with respect to claim 54 and is otherwise overcome by the amendments presented herein.

Given the above-noted amendment to claim 1, applicants submit that one of skill in the art would be fully capable of identifying the glutamic acid residue to the substituted, and would be fully able to carry out the substitution as recited given the teachings of the present application. Applicants submit that this satisfies the enablement requirement for claim 1 and claims 19-22 dependent thereon.

Claims 6, 9, 12, and 13 now depend from allowable claim 53.

For these reasons, the rejection of claims 1, 6, 9, 12, 13, 19-22, and 54 under 35 U.S.C. § 112 (1st para.) for lack of enablement should be withdrawn.

The rejection of claims 1, 6, 9, 12, 13, and 19-22 under 35 U.S.C. § 112 (2^d para.) for indefiniteness is overcome by the amendments presented herein. Specifically, as noted above, claim 1 has been amended to recite the position of the substituted glutamic acid residue with reference to SEQ ID NO: 2. Therefore, claims 1 and 19-22 satisfy the requirements of 35 U.S.C. § 112 (2^d para.).

Claims 6, 9, 12, and 13 now depend from allowable claim 53.

For these reasons, the rejection of claims 1, 6, 9, 12, 13, and 19-22 under 35 U.S.C. § 112 (2^d para.) for indefiniteness should be withdrawn.

This submission is accompanied by a petition for one month extension of time. All fees associated therewith should be charged to deposit account 14-1138. Any overpayment or underpayment should be applied to this same account.

In view of all of the foregoing, applicant submits that this case is in condition for allowance and such allowance is earnestly solicited.

Respectfully submitted,

Date: July 16, 2010

/Edwin V. Merkel/
Edwin V. Merkel
Registration No. 40,087

NIXON PEABODY LLP
1100 Clinton Square
Rochester, New York 14604
Telephone: (585) 263-1128
Facsimile: (585) 263-1600